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EXAMINER	
ORWIG, KEVIN S	

ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,449	ROYERE ET AL.	
	Examiner	Art Unit	
	Kevin S. Orwig	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-54* is/are pending in the application.

4a) Of the above claim(s) *49-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendments and arguments filed Dec. 22, 2008 are acknowledged and have been fully considered. Claims 1-27 are cancelled; claims 28, 31, 32, 36, 37, 44, 46, and 47 are amended; claims 49-54 are withdrawn.

The objection to claim 47 is maintained since no action has been taken to address the issue raised in the previous Office action.

The rejection of claims 28-33 and 36-48 under 35 U.S.C. 103(a) over JANSEN and WESTESEN is maintained as discussed below.

The rejection of claims 28, 34, and 35 under 35 U.S.C. 103(a) over JANSEN, WESTESEN, and RABUSSIER is maintained as discussed below.

No new grounds of rejection are set forth herein.

Claim Objections (Maintained)

Claim 47 is objected to because of the following informalities: the word "the" in line three is awkward and should be deleted. In contrast to applicants' assertion, the amendment to claim 47 does not address nor overcome the objection to the claim. Appropriate correction is required.

Priority

In the response dated Dec. 22, 2008, applicants have attempted to argue the Office's determination of the effective U.S. filing date. The prior Office action stated:

"The earliest effective U.S. filing date afforded the instantly claimed invention has been determined to be Sep. 30, 2004, the filing date of PCT application PCT/FR04/02480 to which the instant national stage 371 application claims priority. Acknowledgment is made of applicant's claim to foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of the French application was filed with the USPTO on Apr. 12, 2006."

Applicants' arguments regarding the priority issue are unclear. Applicants appear to be arguing that the application should be entitled to the date of Oct. 13, 2003 for the U.S. filing date (see pp. 11-12 of the response). In contrast to applicants' allegation, the Office did not deny any priority (foreign or domestic), and it was not stated that applicants were not entitled to the benefit of the French priority date. Rather, applicants' claim to the French foreign priority document was *acknowledged* in the prior Office action (see p. 3 of the Office action dated Aug. 20, 2008, reproduced above). It is noted that the *foreign priority date* and the effective *U.S. filing date* are distinct. The date of a foreign priority document can never be used as a U.S. filing date. See MPEP § 706.02 (see subsection VI. Determining the effective filing date of the application, item (C)).

As properly stated by applicants, the benefit afforded by a proper claim to foreign priority relates to overcoming intervening references: In the case that an intervening reference is applied in a rejection, applicants will be entitled to the foreign priority date for the purpose of overcoming the date of the reference, provided that a certified English

language translation is supplied and it is determined that the corresponding foreign application supports the claims in the manner required by 35 U.S.C. 112, first paragraph. See MPEP § 201.15, which states "The only times during *ex parte* prosecution that the examiner considers the merits of an applicant's claim of priority is when a reference is found with an effective date between the date of the foreign filing and the date of filing in the United States and when an interference situation is under consideration."

Provided that the foreign priority is perfected with a certified English translation of the French document, the examiner agrees that applicants would be entitled to the date of Oct. 13, 2003 for the benefit of a foreign priority date, should intervening art be applied in a rejection. However, the examiner notes that no intervening art has been applied. Applicants incorrectly state that the Office cited Jansen as intervening prior art. Nowhere in the Office action dated Aug. 20, 2008 is such a statement made. As applicants correctly point out (p. 11 of the response), Jansen is not intervening prior art. Thus, while applicants are entitled to the foreign priority date of Oct. 13, 2003 if the appropriate criteria are met as discussed above, the proper effective U.S. filing date was correctly determined to be Sep. 30, 2004 as set forth in the prior Office action. Unless intervening art is applied, it is Sep. 30, 2004 that references must antedate in order to be proper prior art references.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 28-33 and 36-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over JANSEN (U.S. 2004/0071716; Filed Feb. 20, 2002) in view of WESTESEN (U.S. 6,207,178; Issued Mar. 27, 2001).

1. Jansen discloses water-in-oil-in-water (w/o/w) emulsions comprising adjuvants or therapeutical (i.e. active) agents and stabilizing agents (abstract; paragraph [0044]). These emulsions contain a dispersed water-in-oil (w/o) phase (i.e. a lipid phase) in a

continuous aqueous phase (example 3). Jansen teaches the use of emulsifiers (i.e. stabilizing agents), including PEG-30 dipolyhydroxystearate (i.e. Arlacel P135), which comprises two fatty acid chains and one polyethylene glycol (PEG) chain of 30 polyethylene glycol units (examples 1-6). The dispersed lipid phase droplets in these emulsions are from 1-5 μm (example 3), which is considered monodisperse according to the instant specification (paragraphs [0029] and [0039]). Jansen does not teach the use of lipids that are crystallizable as defined in the instant specification.

2. However, Westesen disclose suspensions of solid lipid particles, which are oil-in-water emulsions of dispersed lipid phase particles in a continuous water phase (abstract; examples 1-3). The lipid particles (i.e. the lipid phase) taught by Westesen form matrices that carry bioactive agents (col. 10, lines 20-67). The solid lipid particles are made of fats including di- and tri-glycerides of long chain fatty acids that are solid at room temperature (i.e. crystallizable lipids) (col. 5, lines 23-26; col. 9, lines 20-29). It is noted that the crystallizable lipids may be tripalmitate, a saturated C_{16} fatty acid derivative.

3. Jansen teaches that an improvement over the prior art is to provide emulsions that are stable (abstract; paragraphs [0010], [0030], and [0037]), have utility in parenteral administration (paragraphs [0030] and [0049]) and have utility as vaccines (abstract; paragraphs [0001], [0012], and [0040]). Westesen teaches that the compositions are extremely stable (col. 12, lines 18-19; claim 1) and that they are useful as delivery systems for a variety of administration routes including, *inter alia*, parenteral (e.g. intravenous), nasal, and pulmonary administration as well as useful as vaccines

(abstract; col. 1, line 60 to col. 2, line 12; col. 5, lines 27-32). It is clear that difficulties in obtaining stable, fluid emulsions for the administration routes discussed above were recognized in the art and addressed by both Jansen and Westesen. In light of these teachings, the skilled artisan would have been motivated to include crystallizable lipids in the composition taught by Jansen with the expectation of producing a stable emulsion for the delivery of lipophilic active agents in the oil phase, which would be useful for a variety of administration routes. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to substitute known crystallizable lipid components as taught by Westesen in the emulsions of Jansen to prepare a drug delivery system with the expected result of solving the same problem, reading on instant claims 28, 30, 33, 36, and 37.

4. Instant claim 29 recites the composition of claim 28 in which an inner aqueous phase is dispersed in the dispersed lipid phase. In this situation, the composition is a water-in-oil-in-water (w/o/w) emulsion. Jansen teaches w/o/w emulsions in which an "inner" aqueous phase is dispersed in an oil phase comprising Miglyol 840, which is in turn dispersed in another aqueous phase (example 3), reading on instant claim 29.

5. Westesen teaches that the lipid phase of their compositions may be approximately 11% by weight relative to the total composition weight (see example 2, where 7.84 g lipid phase is dispersed in water to a total weight of 70 g), which is within the range of 0.01-30% by weight, reading on instant claim 31.

6. Jansen teaches the use of Arlacel P135 (i.e. the stabilizing agent) at 3% by weight, which is within the range of 0.001-30% by weight, reading on instant claim 32.

7. The aqueous phases of the emulsions taught by Jansen contain antigens and phosphate buffered saline (PBS) (i.e. a salt). Since PBS contains sodium chloride, it is considered a cryoprotective agent as defined in the instant specification (paragraph [0046]) (example 3), reading on instant claims 38 and 39.

8. Jansen teaches that the bioactive agents may be antigens (i.e. proteins) which are present in the inner water phase. Furthermore, the lipid particles taught by Westesen form matrices that carry bioactive agents (col. 10, lines 20-67). These bioactive agents may be pharmaceutical active principles (col. 10, lines 32-60; col. 14, line 58 to col. 15, line 27), such as, *inter alia*, antibiotics (i.e. antibacterial agents), beta blockers, and vitamins (col. 10, lines 32-60). Westesen also teaches that the bioactive agents may be angiotensin converting enzyme (ACE) inhibitors (col. 10, line 40). Since ACE is an exopeptidase, it is a protease. ACE inhibitors are thus protease inhibitors, reading on instant claims 44-48.

9. Westesen teaches that their compositions may comprise mixtures of bioactive agents (abstract; col. 15, lines 52-53). Thus, these compositions can contain at least two active principles, reading on instant claim 40.

10. In the case of the w/o/w emulsion taught by Jansen (example 3) the lipid phase (i.e. the dispersed w/o emulsion) contains a water soluble active principle (the antigen compounds), reading on instant claim 41.

11. Westesen teaches the use of both water soluble compounds (col. 10, lines 26-31) and sparingly water soluble compounds (col. 14, lines 54-62) as bioactive agents. Westesen also teaches that their compositions may comprise mixtures of bioactive

agents as described above in paragraph 10. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include both a water soluble active principle and a sparingly water soluble active principle in the lipid phase of the emulsions taught by Jansen as needed to produce a drug delivery system to treat multiple conditions or to deliver multiple drugs for the same condition, reading on instant claims 42 and 43.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that the references fail to teach or suggest all of the limitations of claim 28. In support of this argument, applicants further argue that none of the cited references discloses or suggests each and every element of claim 28 (p. 13 of the response).

Applicants are reminded that the rejection was made under 35 U.S.C. 103 (obviousness), and that a combination of references was applied in the rejection. For such a rejection, it is not required that a single reference disclose each element of the claim. Rather, it is the *combination* of references that must provide the requisite teachings. Since applicants have not pointed out any limitation that the *combination* of references fails to teach, it is presumed that applicants are arguing that any one of the individual references does not teach or suggest all of the claim limitations (see first sentence of last paragraph on p. 13 of the response). In response to applicants' arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The prior Office action acknowledged Jansen's deficiency in that it does not teach crystallizable lipids, and relied on Westesen to cure this deficiency as detailed above. Westesen teaches adding crystallizable lipids to an emulsion (abstract; Examples 1-3).

Applicants argue that Jansen teaches away from adding a crystallizable lipid to the inventive compositions (pp. 14-15 of the response).

Applicants' argument that Jansen teaches away from adding a crystallizable lipid is unpersuasive. The MPEP states that to be a true "teaching away", the disclosure must criticize, discredit, or otherwise discourage the solution claimed...." *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). See MPEP § 2122.

Jansen provides no such teaching. It is noted that nothing in Jansen teaches or suggests that crystallizable lipids cannot be used in the inventive compositions. Applicants' argument that Jansen teaches away from crystallizable lipids hinges on the assertion that "adding a solid to the emulsion would automatically lead to an increase of viscosity".

First, other than applicants' assertion, no actual evidence has been provided to demonstrate that this is the case. The MPEP is clear that to be of probative value, any objective evidence should be supported by actual proof, and that attorney arguments cannot take the place of evidence. See MPEP § 716.01(c).

Second, in contrast to applicants' assertion, the evidence of record *supports* the combination of crystallizable lipids in Jansen's emulsions. For instance, as indicated in the prior Office action, both Jansen and Westesen are concerned with stable emulsion compositions that have utility in parenteral (e.g. intravenous) administration and that have utility in vaccines. See paragraphs [0001], [0012], [0030], [0040], and [0049] of Jansen, and abstract; col. 1, line 60 to col. 2, line 12; col. 5, lines 27-32 of Westesen. Given that Westesen's compositions, which contain solid lipid particles (i.e. crystallizable lipids), are intended *primarily* for the parenteral route (col. 5, lines 28-31), it cannot be said that the addition of these same lipids would increase the viscosity of Jansen's compositions, let alone increase the viscosity to such an extent as to make them unsuitable for parenteral administration. Jansen clearly does not teach away from the addition of crystallizable lipids as taught by Westesen.

Third, as stated by applicants on page 14 of the response, if a proposed

modification would render the prior art invention being modified unsatisfactory for its intended purpose or if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings are not sufficient to render the claims *prima facie* obvious. In this case, neither of these situations applies. Rather, both Jansen and Westesen are concerned with substantially similar subject matter, in particular stable emulsions with utility in parenteral administration and vaccines. Westesen teaches that the compositions are extremely stable (col. 12, lines 18-19; claim 1) and that they are useful as delivery systems for a variety of administration routes including, *inter alia*, parenteral (e.g. intravenous), nasal, and pulmonary administration as well as useful as vaccines (abstract; col. 1, line 60 to col. 2, line 12; col. 5, lines 27-32). It is clear that difficulties in obtaining stable, fluid emulsions for parenteral administration were recognized in the art and addressed by both Jansen and Westesen. In light of these teachings, the skilled artisan would have been motivated to include crystallizable lipids in the composition taught by Jansen with the expectation of producing a stable emulsion for the delivery of lipophilic active agents in the oil phase, which would be useful for a variety of administration routes. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to substitute known crystallizable lipid components as taught by Westesen in the emulsions of Jansen to prepare a drug delivery system with the expected result of solving the same problem, namely preparing a stable emulsion for the delivery of fat-soluble active agents useful for, *inter alia*, parenteral delivery. A *prima facie* case of obviousness has been established.

Applicants argue that suspensions of solid lipids are not equivalent to lipid emulsions (p. 15 of the response).

While this argument is acknowledged, no evidence has been put forth to support the assertion that any differences in the two types of suspensions would render the combination of Jansen and Westesen inoperable. Rather, the evidence presented above supports the use of both types of compositions in parenteral administration forms, and it would be routine experimentation for the skilled artisan to resolve any differences between the two to successfully combine these elements. Solid lipids would clearly not prevent Jansen's compositions from functioning properly even given differences in the way the components must be handled.

Applicants argue that the monodisperse nature of Jansen's compositions does not absolutely imply that this lipid phase would be monodisperse if solid lipids were substituted (p. 15 of the response).

Again, no evidence has been put forth to support the assertion that the substitution of crystallizable lipids would absolutely lead to a non-monodisperse lipid phase. In contrast, Westesen teaches that the solid particles are of submicron size, predominantly from 0.05 to 0.5 nm. Thus, the skilled artisan would be able to prepare monodispersed lipids for Jansen's compositions using the crystallizable lipids of Westesen. As noted above and in the prior Office action, Westesen teaches crystallizable lipids that are solid at room temperature and have melting points ranging from approximately 30 to 120 °C (col. 9, lines 20-31). This teaching matches the definition pointed to by applicants at p. 7, line 37 to p. 8, line 1 of the application as filed

(paragraph [0030] of the pre-grant publication).

Claims 28, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen and Westesen as applied to claims 28-33 and 36-48 above in further view of RABUSSIER (U.S. 3,258,326; Issued Jun. 28, 1966).

12. The composition of instant claim 28 is taught by Jansen and Westesen as applied above. Neither Jansen nor Westesen teaches the use of a thickener or alginic acid salts.

13. However, the use of alginates as components in emulsions is well-known. For instance, Rabussier discloses formulations comprising stable oil-in-water emulsions (col. 2, line 31) and hydrophilic colloids (col. 2, lines 25-28) for delivery of active agents (col. 2, lines 19-22). The hydrophilic colloids taught by Rabussier may be alginates that are added to the water (i.e. the aqueous phase) to maintain stability of the suspension (col. 1, lines 34-42; col. 3, lines 63-72; claim 7). Furthermore, Rabussier teaches that the alginate may be used in 0.2% by weight (example 4). Since alginates were known in the art in the instantly claimed weight % range, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include this known component as a stabilizer in the composition taught by of Jansen and Westesen to prepare a more stable drug delivery system, reading on instant claims 34 and 35.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject

matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that Rabussier fails to rectify the alleged teaching away of Jansen (p. 16 of the response).

This argument regarding Jansen's alleged teaching away has been discussed *supra* and is incorporated herein by reference. Jansen does not teach away from the inclusion of crystallizable lipids.

Applicants further argue that the teachings of Rabussier are distinct from that of the instant invention.

Applicants are reminded that the rejection was made under 35 U.S.C. 103 (obviousness), and that a combination of references was applied in the rejection. It is the *combination* of references that must provide the requisite teachings. In response to applicants' arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The

combination of Jansen, Westesen, teaches all of the elements allegedly missing from Rabussier.

Applicants admit that Rabussier teaches adding an alginate to lipid emulsion compositions (p. 17 of the response), which is exactly what Rabussier was relied upon to teach. Thus, applicants' arguments regarding Rabussier are unpersuasive.

Summary/Conclusion

Claim 47 is objected to; claims 28-48 are rejected; claims 1-27 are cancelled.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-

5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/David J Blanchard/
Primary Examiner, Art Unit 1643